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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,759	07/10/2001	Avi Ashkenazi	10466/59	9581

7590

09/23/2002

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EXAMINER

MOSHER, MARY

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 09/23/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/902,759

Applicant(s)  
Askenazi et al

Examiner  
Mosher

Art Unit  
1648



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 8/25/2002, 7/10/2001, 2/1/2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 39-44 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 9 6) ☐ Other:

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## **DETAILED ACTION**

### ***Priority***

According to the priority statement of July 10, 2001, it appears that priority is being claimed to a large number of utility and provisional applications. These applications appear to be drawn to unrelated subject matter and are either not available for consideration or for which consideration to determine support for the instantly claimed subject matter would require an undue burden. Accordingly, the subject matter defined in claims 39-44 has an effective filing date of July 10, 2001, that of the instant application.

Applicants are requested to provide the serial number and specific page number(s) of any parent application to which priority is desired which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession and fully enabled of prior to July 1, 2001.

### ***Claim Rejections - 35 USC § 112***

Claims 39-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 39-44 are drawn to an antibody which binds the polypeptide shown in Figure 17 (SEQ ID NO:39, PRO246). The specification states, on pages 145-147, that anti-PRO antibodies may be used in diagnostic assays or for affinity purification of PRO proteins, or administered for treatment of various disorders. The specification identifies PRO246 as a

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membrane-bound polypeptide having homology to the human Cocksackie-adenovirus receptor and to various tumor antigens, and states that the polypeptide “may be a novel cell surface virus receptor or tumor antigen” (page 8). On page 101, the specification teaches that “a portion of the PRO246 polypeptide has a significant homology with the human cell surface protein HCAR.” The specification speculates on page 131 that the PRO246 polypeptides which serve as cell receptors for one or more viruses may be employed therapeutically, and those PRO246 polypeptides which serve as tumor specific antigens may be exploited as therapeutic targets for anti-tumor drugs. On page 244, analysis of the expression of PRO246 concludes that the protein is expressed in certain fetal and adult tissues, especially fetal vascular endothelium, and not obviously expressed at higher levels in tumor vascular endothelium. The specification therefore does not teach what virus, if any, interacts with the putative receptor, nor teach any disease or disorder which can be diagnosed using the PRO246 protein. In the absence of such information, one skilled in the art has no guidance as to how to use a PRO246 protein or an antibody binding a PRO246 protein, for any purpose other than further research. Considering the lack of information regarding any specific disease state or disorder which can be diagnosed with PRO246, and the lack of information regarding viruses which associate with PRO246, and the absence of any evidence that any virus actually interacts with the putative receptor, it is concluded that undue experimentation would be required to use the claimed antibody.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 39-44 are rejected under 35 U.S.C. 102(e2) or under 35 U.S.C. 102 (b) as being anticipated by Lal et al 5,942,606. Lal et al teaches a polypeptide, ACVRP, 100% identical to SEQ ID NO:39. Lal et al also teaches antibodies against the polypeptide, see for example column 18, line 64 through column 20, line 11; column 24, lines 20-49; and column 35, lines 10 -34.

The following documents are cited as of interest, in disclosing polypeptides similar to or identical to SEQ ID NO:39. Copies are not provided, since each is exceedingly bulky.

Reference	Protein
WO200011015	vc51-1, SEQ 38
EP1067182	PSEC0086, SEQ 84
WO200149728, US20020061567	HP10801
WO200125427	Human shear stress-response protein SEQ 144.
WO9958660	gene 29
WO200078808, US6406884	INTERCEPT 258, SEQ 28.

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is (703) 308-2926. The examiner can normally be reached on Monday -Thursday and alternate Fridays from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is now (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

August 28, 2002

  
**MARY E. MOSHER  
PRIMARY EXAMINER  
GROUP 1800**  
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